REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1 to 10 and 12 to 27 are pending with entry of this amendment. Claims 11 and 28 being previously cancelled. Claims 1, 2, 9, 10, 15, 16 and 17 are amended herein. Claims 18 to 27 have been withdrawn in response to a restriction action made final. These amendments introduce no new matter and support is replete throughout the specification. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

With respect to claims 1, 9 and 15, support for the aspect of an O-RS with conservative variations at least 80% sequence homology to SEQ ID NO.: 18 can be found throughout the specification. For example, see specification at paragraphs 119, 120, 138; and in the section titled Conservative Variations starting at paragraph 103.

With respect to claims 2, 9 and 15, support for amino acids at positions 32 and 158 can be found throughout the specification. For example, see specification at paragraph 164 and in Table 1.

Applicants submit that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the amendments is respectfully requested.

The Information Disclosure Statement.

Applicants note with appreciation the Examiner's thorough consideration of the references cited in the Information Disclosure Statement (Form 1449) submitted on April 5, 2005.

Claim Objections.

Applicants appreciate Examiner's reconsideration and agreement to examine restricted Groups 1-6 together. Claims 1-10 and 12-17 are objected to because they include

SEQ ID NOs: 19 and 20. Applicants have amended the claims herein and make these amendments in order to expedite examination and issuance of a Notice of Allowance

35 U.S.C. §112, First Paragraph.

Written Description. Claims 1 to 10 and 12 to 16 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. To the extent the amended claims are deemed not to comply with the written description requirement, Applicants traverse.

The "written description" requirement has been formulated in a number of different ways over the years. One relatively clear current concise statement of the written description requirement set forth by the courts is as follows:

> The [written description] requirement may be satisfied if claim terms 'readily convey distinguishing information concerning their identity, such that one of ordinary skill in the art could visualize or recognize the identity of a member of the genus.' *Amgen Inc. v. Hoescht Marion Roussel, Inc.* 65 USPQ2d 1385 (Fed. Cir. 2003).

The Action argues that the pending claims fail to meet the written description requirement because, e.g., the claims are "described only functionally and no structural correlation can be inferred from the recited 'ORS with at least 50% efficiency relative to the structure of SEQ ID NO: 18'"; and that the "'conservative variants' can comprise ... 5 or more amino acid variations ... Thus any number of variations is encompassed in the claims." However, in light of current amendments, these rejections are rendered moot.

The current claim 1 no longer includes the aspect requiring efficiency comparison to the provided sequence. Further, the conservative variations are now limited to conservative variations (described, e.g., in the Orthogonal Aminoacyl-tRNA S Synthetase (O-RS) section starting at paragraph 66; and the Conservative Variations section starting at paragraph 103) thereof comprising at least 80% sequence identity (described, e.g., in the Sequence Comparison, Identity, and Homology section starting at paragraph 119).

Because the currently amended claims are described in the original description so that one of skill would recognize that the Applicants were in possession of the claimed invention, Applicants respectfully request the written description rejections be withdrawn.

Enablement. Claims 1 to 10 and 12 to 16 were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. To the extent that the currently amended claims continue to be deemed lacking enablement, Applicants traverse.

To be an enabling disclosure under § 112, first paragraph, a patent must contain a description that enables one skilled in the art to make and use the claimed invention. That some experimentation is necessary does not constitute a lack of enablement; the amount of experimentation, however, must not be unduly extensive. See *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Whether undue experimentation is required by one skilled in the art is typically determined by reference to eight factors considered relevant to the inquiry: (1) quantity of experimentation necessary; (2) amount of guidance presented; (3) presence of working examples; (4) nature of the invention; (5) state of the prior art; (6) relative skill of those in the art; (7) predictability of the art; and (8) breadth of the claims. See id.

The present rejections were based on the argument that the claims do "not reasonably provide enablement for any ORS molecule comprising any ORS from any source with any structure ..." Applicants believe the known art, in combination with the teachings of the original specification reasonably enabled the original claims. However, in the interest of cooperation and to expedite prosecution of the application, claims have been currently amended to structurally related embodiments easily practiced without undue experimentation.

The Action, at page 9, alleged inadequate teachings of "sequence identity", "specific structure" and "how to make" the O-RS aspect of the claims. Applicants believe the new limitations amended into the claims, including, e.g., 80% sequence identity to the provided functional structure, addresses these concerns.

The experimentation required to practice the invention, as currently claimed, would be minimal. One of skill in the art can readily copy the provided sequences, including conservative variations, using ordinary skill and peptide structure analysis software to provide a reasonable probability of success in each effort. Applicants note that the monoclonal antibodies of Wands were found by the Court to be enabled even though no structural information was provided and most of his experimentation resulted in non-

functional clones. Wands provided three representative antibodies - Applicants have provided three representative O-RSs. In *Wands*, the skill in the art of providing monoclonal antibodies was not mature at the time but "the methods required to practice the invention [were] known." This is precisely true for the present case as well. Every step used to produce the claimed compositions is known and available, though some, such as the well described positive-negative screen combine several known methods to achieve the screen. In *Wands*, the observed 2.8% rate of success in screening for antibodies was found to provide adequate predictability. Here, structural information is provided to guarantee success. Even experimentation with the limited conservative amino acid variations would be expected to provide an O-RS with measurable activity in most cases. In *Wands*, the claims essentially covered the entire universe of possible antibodies, including any isotype, functioning to specifically bind Hepatitis B surface Antigen. Here, the O-RS aspect is currently limited to a known functional structure and minor variant structures with a high expectation of functionality. Applying the facts and holding of *In re Wands* to the facts of the present case, one can only reasonably conclude that the present amended claims are enabled.

Because the claims are enabled, Applicants respectfully request withdrawal of the rejections for alleged lack of enablement.

35 U.S.C. §102.

Claims 1 to 10 and 12 to 16 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Schultz (7,045,337). To the extent the rejection is deemed applicable to the amended claims, Applicants traverse.

In order for a reference to anticipate an invention, the reference must teach each and every element of the claimed invention. That is, in order for a reference to anticipate an invention, anticipation requires that "all limitations of the claim are found in the reference, or 'fully met' by it." *Kalman v. Kimberly-Clark Corp.*, 218 USPQ 781, 789 (Fed. Cir. 1983).

The Action alleges Schultz '337 teaches "a cell composition comprising an ORS that aminoacyletes an OtRNA with p-acetyl-L-phenylalanine (claim 8). [But acknowledges that n]o specific structure of an ORS identical to SEQ ID No.: 18 is taught in Schultz ...." The present claims are currently amended to include acknowledged novel

structures in the O-RSs. Therefore, Applicants respectfully request withdrawal of the rejections for alleged anticipation based on Schultz '337.

Double Patenting.

Claims 1 to 10 and 12 to 16 have been rejected based on the judicially created doctrine of obviousness-type double patenting in light of claims 22 and 23 issued in U.S. patent 6,927,042, to Schultz, et al.

However, Applicants note that the present invention has ownership in common with the cited '042 patent to Schultz, et al. In the spirit of cooperation and in order to expedite the present application, Applicants will file a terminal disclaimer should the present claims be found otherwise allowable.

CONCLUSION

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 769-3510 to schedule an interview.

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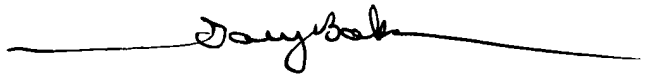
Respectfully submitted,



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Attachments:

1) A petition to extend the period of response for **2** months;
2) A transmittal sheet;
3) A fee transmittal sheet; and,
4) A receipt indication postcard